



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,260	05/18/2005	Timo Pulli	3501-1097	5730
466 7590 02/26/2008 YOUNG & THOMPSON 209 Madison Street Suite 500 ALEXANDRIA, VA 22314			EXAMINER COOK, LISA V	
			ART UNIT 1641	PAPER NUMBER
			MAIL DATE 02/26/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/535,260

**Applicant(s)**

PULLI ET AL.

**Examiner**

LISA V. COOK

**Art Unit**

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 7-17 and 21-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION*****Amendment Entry***

1. Applicant's response and amendment filed 12/3/07 is acknowledged. In the amendment filed, new claims 26-33 were added. Currently claims 1-33 are pending.

***Election***

2. Applicant's election with traverse of Group I (claims 1-6, 18-20 and 26-33) in the reply filed on 12/3/07 is acknowledged. The traversal is on the ground(s) that unity of invention was found in the international application and the examination of all the groups represents no undue burden. This is not found persuasive because 37 CFR 1.475 section II allows for the reconsideration of unity based on results of prior art searches.

See "Where a search of the prior art is made, an initial determination of unity of invention, based on the assumption that the claims avoid the prior art, may be reconsidered on the basis of the results of the search of the prior art".

In the instant application, the search of the prior art resulted in the reference of Self et al. (Clinical Chemistry, Vol.40, No.11, pages 2035-2041, 1994) disclosing a dual antibody reagent-pair being applicable in noncompetitive immunometric assay systems. The assay is based on the interaction of a primary antibody with its ligand in order to form new binding sites, recognizable by a second antibody - which then binds to form a detectable complex. See abstract. The antibodies (fragments) are produced by various procedures. See page 2036 - 2<sup>nd</sup> column.

Although Self et al. are silent with respect to antibody production from a recombinant library, these procedures were well known in the prior art. For example, see the reference to Arai et al. (Protein Engineering, Vol.13, No.5, pages 369-376, 2000).

Accordingly, the technical feature recited in claims 1-25 is not a contribution over the prior art. The groups set forth below are not so linked as to form a single general concept under PCT Rule 13.1.

With respect to undue burden, it is noted that one indication of the burdensome nature of the search involved is that different searches and issues are involved in the examination of each group. Group I is drawn to antibody-binding detection procedures, Group II is drawn to a reagent pair, Group III is drawn to test kits, while Group IV are drawn to recombinant binding proteins. The literature search, particularly relevant in this art, is not coextensive and is much more important in evaluating the burden of the search (art here is antibody assays and recombinant production procedures). Therefore the search for all the groups is deemed burdensome.

3. The requirement is still deemed proper and is therefore made FINAL.
4. Claims 7-17 and 21-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/3/07. Currently claims 1-6, 18-20 and 26-33 are under consideration.

*Please note: The newly added claims require the following Restriction Requirement:*

*Election/Restrictions*

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

6. Claims 27, 28, 30 and 31 include sequences identification numbers. With respect to the separate amino acid structures, they bear distinct structural or biochemical properties having different binding epitopes (Specification references sequence id. Nos. 1-5). **Therefore, each disclosed patentably distinct amino acid sequence is considered a separate invention.** See Official Gazette 1232 OG 242(116) March 21, 2000. Therein the O.G. notice permits the examiner to examine up to ten sequences per application based on the use of US PTO resources. Resources are now stretched to the limit, such that only one sequence should be searched per application. It is recognized that although the search for the inventions may overlap they are not totally co-extensive, where by the search for one would fully encompass the search for the others.

7. Applicant is required to select one sequence/sequence combination for consideration as the first binding partner and one sequence/sequence combination for the second binding partner. The species are as follows:

- I. For the first binding partner select one,
- A. comprising SEQ ID NO:1 and SEQ ID NO:2 (claims 27 and 28)
  - B. comprising SEQ ID NO:3 and SEQ ID NO:4 (claims 27 and 28)
  - C. comprising aa 3 to 108 of SEQ ID NO:1 and aa 4 to 123 of SEQ ID NO:2 (claim 30 and 31)
  - D. comprising aa 3 to 108 of SEQ ID NO:3 and aa 4 to 123 of SEQ ID NO:4 (claim 30 and 31)
- II. For the second binding partner select one,
- E. comprising SEQ ID NO:5 (claim 26)
  - F. comprising aa 3 to 120 and 140 to 246 of SEQ ID NO:5 (claim 29)
8. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.
- Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).
9. The following claim(s) are generic: 1-6, 18-20, and 32-33.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group TC 1600 whose telephone number is (571) 272-1600. The Group 1641 Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Lisa V. Cook/  
Primary Examiner, Art Unit 1641  
2/18/08*